510(k) Summary

SEP 17 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K0101366

A. Submitter:

Chromogenex Technologies Limited
Units 1-2 Heol Rhosyn
Parc Dafen
Llanelli
Carmarthenshire SA14 8QG
UK

Phone: +44 (0) 1554 755444
Fax: +44 (0) 1554 755333

Contact: Mr Peter R Bevan (Quality Manager)

Date Prepared: May 2010

B. Device Names:

Classification name	Massager, vacuum, Light Induced Heating
Common/usual name	Massager / shaper
Proprietary name	i-lipo™ Ultra System

C. Predicate Devices:

Biocellulase Smoothshapes – K061603
Meridian Co. Ltd Lapex BCS – K081962

D. Device Description:

The i-lipo™ Ultra System consists of a main unit, and applied parts (massage head with rollers and various laser diode cluster probes and pads). The Main Unit contains the mains input, fuses, power supply, pump, relay, control circuits, LCD display, membrane function buttons, emergency stop, and key switch. The massage head, and cluster probes and pads, which are placed against the patients skin, contain the rollers, and Laser diodes. Laser light provides topical heating which increases tissue temperature, and the rollers in combination with the vacuum mechanically manipulate the tissue.

E. Intended Use:

The Chromogenex Technologies Limited i-lipo™ Ultra Vacuum Massage System is indicated for the temporary relief of minor muscle aches and pain, temporary relief of

muscle spasms, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.

The i-lipo™ Ultra Treatment Pads and Probes are indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasms, and temporary improvement of local blood circulation.

F. Comparison with the Predicate Devices:
The i-lipo™ Ultra is substantially equivalent to the predicates with respect to intended use and technological characteristics.

G. Clinical Testing
Skin temperature measurements were made to support the performance of pads and probes as thermal heating systems for pain relief.

H. Non Clinical Testing
Safety testing is to be carried out to IEC and UL 60601-1 Medical Electrical Equipment Part 1 – General Requirements for Safety; Collateral Standard : Safety Requirements for Medical Electrical Systems, IEC 60601-2-22 Specification for diagnostic and therapeutic laser equipment, CSA C22.2 Canadian Electrical code Part II, and IEC 60601-1-2 – Collateral Standard : Electromagnetic Compatibility.

I. Conclusion
Based on the technological characteristics and the non clinical testing, the i-lipo™ Ultra is substantially equivalent to the above names predicate devices, for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Chromogenex Technologies, Ltd.
% Mr. Peter R. Bevan
Units 1 & 2 Heol Rhosyn
Parc Dafen
Carmarthenshire SA14 8QG
United Kingdom

SEP 17 2010

Re: K101366
Trade/Device Name: i-lipo™ Ultra System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: NUV, ILY
Dated: September 13, 2010
Received: September 15, 2010

Dear Mr. Bevan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

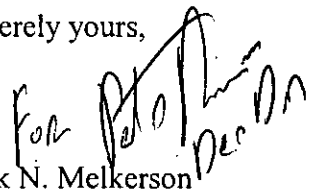
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101366

Device Name: i-lipo™ Ultra System

SEP 17 2010

Indications for use:

The i-lipo™ Ultra - Vacuum Massage System - is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasms, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite.

The i-lipo™ Ultra -Treatment Pads and Probes - are indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasms, and temporary improvement of local blood circulation.

Prescription Use __X___ (21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Neil RP Ogden for mam

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101366